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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,803	07/01/2003	Eric Gervais	GOUD:031US	5065
7590 02/17/2009				
Michael R. Krawczsnek Fulbright & Jaworski L.L.P. Suite 2400 600 Congress Avenue Austin, TX 78701			EXAMINER LEVY, NEIL S	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 02/17/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/611,803

## Applicant(s)

GERVAIS ET AL.

## Examiner

NEIL LEVY

## Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 6 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6 & 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6,35 stand rejected under 35 U.S.C. 103(a) as being obvious over MEZAACHE et al in view of WO 97/48384 and ORIFER F Prenatal Vitamin Supplement for pregnant women, September 25, 1996.

MEZAACHE provides embossed tablets [0005] of the instant drugs [0063], and many others, But does not show figures.

ORIFER F is prenatal vitamin supplement that bears pregnancy friendly indicia on the packaging. The vitamin supplement comprises at least one active ingredient and is intended to be administered to pregnant woman as is indicated by the graphical representation of a pregnant woman on the packaging.

WO '384 teaches it is well known in the art to imprint markings or text on dosage forms such as tablets and capsules in order to minimize errors associated with administration of pharmaceuticals (page 2, lines 17-31).

Thus it would be obvious to one of ordinary skill to imprint pregnancy friendly indicia such as the one displayed on the packaging material of ORIFER F by the artisan.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize a graphic design on a drug tablet to indicate prenatal consumption was acceptable ,to use one of MEZAACHE modified with a figure of ORIFER, in order to enhance acceptability & consumption by pregnant women . The methodology was well known, as exemplified by WO '384.

***Response to Arguments***

Applicant's arguments filed 11/25/-08 have been fully considered but they are not persuasive. Applicant argues . MEZAACHE, is not prior art- it is, under 35 USC 103(a), based on 102(e), as the filing date predates instant filing date. As to the declaration, it addresses applicant's rationale for the indicia, but NOT the claimed composition of pyridoxine hydrochloride with doxylamine succinate. Thus, the obviousness rejection stands. One in the art would choose the combination , with every expectation of effective results, since MEZAACHE states [0063- first line] that the active ingredients may be combined, & KSR had shown that it would be obvious to consider a finite number of examples to test with expectation of success.

The arguments are directed to a composition , requiring that examination of the composition by the possible user would result in a perception perceived by applicant.

The composition is seen as obvious; the perception expected not necessarily the one claimed by applicant.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NEIL LEVY/  
Primary Examiner, Art Unit 1615

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